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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/053,871	01/24/2002	James D. Thacker	38599.0012	5347

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HELLER EHRMAN WHITE & MCAULIFFE LLP  
SUITE 300  
101 ORCHARD RIDGE DR.  
GAITHERSBURG, MD 20878-1917

EXAMINER

HINES, JANA A

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 03/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/053,871

Applicant(s)

THACKER, JAMES D.

Examiner

Ja-Na Hines

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 January 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 January 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.                      6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Priority***

1. If applicant desires priority under 35 U.S.C. 119(e) based upon a previously filed application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph unless it appears in an application data sheet.

### ***Drawings***

2. The drawings filed on January 24, 2002 are unacceptable and subject to correction of the informalities indicated on the attached "Notice of Draftsperson's Patent Drawing Review," PTO-948. In order to avoid abandonment of this application, correction is required in reply to the Office action. The correction will not be held in abeyance.

### ***Specification***

3. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

***Claim Objections***

4. Dependent claim 27 is drawn to the solid support is supplied with said capture antibodies immobilized thereto; however claim 26 already states that capture antibodies are affixed to the solid support.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claim 1 is drawn to a method for the rapid typing or enumeration of microorganisms comprising an immobilization step; several contact steps wherein metabolism of said substrate by microorganisms produces a marker; a digestion step; several addition steps; a detection step; and a determination step.

The specification and claims lack sufficient written description of the generically claimed marker. The marker is not defined. The claims merely state that

microorganisms produce the marker and antibodies can be specific for the marker. The description of the marker, does not describe the marker itself. The fact that microorganisms produce it or that antibodies can be specific for it is a purely functional distinction. Thus, a description of the marker by what it binds to or what can produce it is insufficient. The claims fail to identify what the marker is.

A skilled artisan cannot envision the detailed structure of the marker, thus conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. An adequate description requires more than a mere statement that it is part of the invention. The marker itself is required and should be identified as opposed to any broadly claimed marker. It is noted that even where there is an actual reduction to practice, which may demonstrate possession of an embodiment of an invention, it does not necessarily describe what the claimed invention is. The instant specification and claims broadly claiming any marker described by its source of production does not describe the claimed marker itself.

See also, *In The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), where the court held that a generic statement that defines a genus of nucleic acids by only their functional activity does not provide an adequate description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus.

Therefore the full breadth of the claims fail to meet the written description provision of 35 USC 112, first paragraph.

6. Claims 1-35 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is an enablement rejection.

Claims 1-35 are drawn to a method for the rapid typing or enumeration of microorganisms comprising an immobilization step; several contact steps; a digestion step; several addition steps; a detection step; and a determination step and a kit.

The claims are so broad that they encompass the rapid typing and enumeration of every type of microorganism, however applicants have not described such a method. Moreover, applicants claimed methods perform the rapid typing or enumeration with only one capture antibody, one primary antibody and one secondary antibody. The instant specification fails to provide a method wherein microorganism is rapidly typed or enumerated with only one primary antibody that binds to an unknown or undescribed marker.

The specification fails to teach that every type of microorganism can be used within the claimed method. There is no teaching that contacting the contents of said sample with an amount of substrate will produce a marker in a parasite, virus, fungus, yeast and all bacteria that are all types of microorganisms. Moreover, there is no

teaching that all forms of microorganisms can be typed or enumerated with said method.

The specification teaches that the existence of antibodies specific for specific types of bacteria are known in the art to aid in the determination of a specific type of bacterial species, however the claims fail to recite using different antibodies to detect or rapidly type. It is noted that there is no teaching of how to enumerate microorganisms with only one primary antibody specific to an unknown marker.

There is no written description of any method steps which teach such broadly claimed methods. There are no examples that teach the rapid typing of each and every type of microorganism or its enumeration. The claims fail to recite the necessary method steps, such as what the capture antibody is capturing; or how adding a primary and secondary antibody will detect anything when now contact step is recited; and how the determination of type or quantity of the microorganisms occurs. There are no data showings that the unidentified marker will be found in every microorganism.

The specification does not provide substantive evidence that the claimed method is capable of identifying any marker in all microorganisms. This demonstration is required for the skilled artisan to be able to use the claimed method for their intended purpose of rapid typing or enumeration of microorganisms.

Without this demonstration, the skilled artisan would not be able to reasonably predict the outcome of the method for rapid typing or enumeration of microorganisms. Furthermore, the specification fails to adequately disclose a description of the method for rapid typing or enumeration of microorganisms, thus a skilled artisan would be

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required to de novo locate, identify and characterize the claimed method and markers. Accordingly, this would require undue experimentation given the fact that the specification is lacking in teachings as to a method for rapid typing or enumeration of microorganisms.

7. Claims 1-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In particular, claims 1 and 13 are vague and unclear. It is noted claim 1 immobilizes a single capture antibody on a solid support and contacts the capture antibody with a sample, however the claim fails to recite what the capture antibody is specific for, i.e., what it will capture. No other steps refer to the capture antibody, therefore the claim fails to teach how the capture antibody will capture or detect anything.

The claims refer to digesting microorganisms, however the claims fail to further recite what happens with the digested microorganisms, therefore it is unclear what this step is accomplishing.

The claims refer to contacting a single primary antibody specific for the marker, however the claims fail to require contact between the primary antibody and the unidentified marker. It is unclear how one would know what the primary antibody should be specific for since the marker has not been identified. Claim 1 then states that a secondary antibody specific for the primary antibody should be added.



It is unclear where the antibodies are being added, i.e., the solid support or elsewhere. Again there is no contact step between the secondary antibody and the primary antibody.

Moreover, the phrase "and conjugated to a reporter molecule " is unclear. Is the secondary antibody conjugated to a reporter molecule, if so, the claims should clearly recite such. Then the claim detects the secondary antibody, but it is noted that the secondary antibody has not been contacted with anything; therefore it is unclear how determination can occur.

Moreover, the claims fail to recite the use of multiple antibodies specific for different types of microorganisms, thus it is unclear how the microorganisms can be typed. Furthermore, it is unclear how one could determine what type of microorganism is present in the sample unless one already knew what microorganisms were in the sample and what antibodies to use to detect such microorganisms. Yet the claims do not recite such steps. Thus, the claims are so unclear, that the metes and bounds cannot be ascertained. Clarification is required.

The term "rapid enumeration" or "rapid detection" in the claims is a relative term which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. There is no basis for comparison of the definition of rapid. Therefore the metes and bounds of the claims cannot be ascertained.

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8. Claims 12 and 23 are unclear. Claims 12 and 23 recite that the microorganisms are digested prior to their contact with said capture antibody, however it is noted that there is no step that requires the capture antibody to bind the microorganisms, i.e., the claims fail to recite what the capture antibody will capture.

9. Claim 13 is unclear. It is unclear how the primary antibody can be detected if it is not conjugated or bound to a detectable label, since detectable labels are needed to detect the primary antibody.

10. Claim 33 is rejected. Acronyms like NAD<sup>+</sup> must be spelled out when used for the first time in a chain of claims.

11. Claim 34 is indefinite. The kit fails to recite a detectable label which would allow the rapid detection and enumeration of microscopic organisms.

12. Claims 1-24 are rejected as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MEP. § 2172.01. The claims lack essential contact steps and correlation steps that correlate the detected reporter molecule to determining the type or quantity of microorganisms as previously discussed.

### ***Double Patenting***

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 1-35 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-28 of U.S. Patent No.6,344,332. Although the conflicting claims are not identical, they are not patentably distinct from each other. Claim 1 of the instant application is drawn to a method for the rapid typing or enumeration of microorganisms comprising an immobilization step; several contact steps; a digestion step; several addition steps; a detection step; and a determination step.

US Patent 6,344,332 is also drawn to a method for the detection of the presence of less than 100 cfu/ml of microorganisms comprising the same basic steps as

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described by the instant application including several contact steps; a digestion step; and a detection step.

The instant claims further recite detecting the presence of less than 1000 colony forming units per ml or less of microorganisms; wherein less than two hours; using the same reporter molecules, substrates and sample types as US Patent 6,344,332.

The method of the instant claim is drawn to the same invention as described by the claims of US Patent 6,344,332. Moreover, no more than skill is required to the economically efficient and commercially available products into a kit. Therefore the instant claim is rejected in view of US Patent 6,344,332.

#### ***Prior Art***

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Abbas et al., teach a method of detecting, identifying and enumerating microbes in biological and non-biological samples.


16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 703-305-0487. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 703-308-3909. The fax phone numbers

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for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ja-Na Hines   
March 10, 2003

  
**LYNETTE R. F. SMITH**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**